Approval Date: March 24, 1997

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-192

B. Sponsor

Phoenix Scientific, Inc
3915 South 48th Street Terrace
P.O. Box 6457
St. Joseph, MO 64506-0457

C. Proprietary Name

Sulfadimethoxine 12.5% Oral Solution

D. Established Name

sulfadimethoxine B.P.

E. Pharmacological Category

Antibacterial

F. Dosage Form

Oral solution

G. Amount of Active Ingredient

Each mL contains 125 mg of Sulfadimethoxine (base)

H. How Supplied

3.785L (1 gal) multiple dose bottle

I. Dispensing Status

OTC

J. Dosage Regimen

Broiler and replacement chickens

Concentration: 0.05%. 1 fl oz to 2 gallons of drinking water.

Meat-producing turkeys

Concentration: 0.025%. 1 fl oz to 4 gallons of drinking water.

Dairy calves, Dairy heifers, and Beef cattle

Concentration: 0.025%. 1 fl oz to 4 gallons of drinking water.

K. Route of Administration

Orally in drinking water

L. Species/Class

Chickens, Turkeys and Dairy Calves, Dairy Heifers and Beef Cattle

M. Indication

Broiler and Replacement Chickens- Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

Meat-Producing Turkeys- Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

Dairy Calves, Dairy Heifers and Beef Cattle- Use for the treatment of shipping fever complex, and bacterial pneumonia associated with *Pasteurella* Spp. sensitive to sulfadimethoxine; and calf diptheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.

N. Pioneer Product

Albon® 12.5% Concentrated Solution manufactured by Hoffmann-La Roche (NADA 031-205)

II. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product).

For certain dosage forms, the agency grants a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990: fifth GADPTRA Policy Letter). In lieu of *in vivo* bioequivalence testing, the bioequivalence of the generic product to the pioneer product is based on the demonstrated chemical equivalence to the pioneer product.

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver January 11, 1996 from conducting an *in vivo* bioequivalence study with Sulfadimethoxine 12.5% Oral Solution. The generic and pioneer products are solutions with the same active and inactive ingredients in the same concentrations.

III. HUMAN FOOD SAFETY

A. Tolerance

The tolerances established for the pioneer product apply to the generic product. Tolerances are established for residues of sulfadimethoxine in uncooked edible tissues of chickens, turkeys, and cattle as follows: 0.1 part per million (negligible residue). In milk at 0.01 part per million (negligible residue)(21 CFR 556.640).

B. Withdrawal Time

When a waiver from the requirement of an in vivo bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for sulfadimethoxine 12.5% Oral Solution is established under:

21 CFR 520.2220a(e)(1)(iii) Broiler and Replacement Chickens- 5 days before slaughter.
21 CFR 520.2220a(e)(2)(iii) Meat-Producing Turkeys- 5 days before slaughter
21 CFR 520.2220a(e)(3)(iii) Dairy Calves, Dairy Heifers and Beef Cattle- 7 days before slaughter.

C. Regulatory Method for Residues

No new method required for this approval.

D. Human Safety Relative to Possession, Handling and Administration

Labeling contains adequate caution/warning statements.

IV. AGENCY CONCLUSIONS

This is an abbreviated new animal drug application (ANADA) filed under Section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Bioequivalence of this generic animal drug, Sulfadimethoxine 12.5% Oral Solution, was established by demonstration of chemical equivalence to the pioneer product, Hoffmann-La Roche's Albon® 12.5% Concentrated Solution (NADA 31-205)

This generic product and the pioneer product have identical labeling indications for the gallon bottle for use in chickens, turkeys and cattle. The route and method of administration of the two drugs are identical. Both drugs are administered orally in the drinking water. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy promulgated to implement section 512(b)(2) of FFD&C Act, no additional safety, efficacy, or *in vivo* bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Sulfadimethoxine 12.5% Oral Solution, is safe and effective for its labeled indications when used under its proposed conditions of use.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.